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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/743,695	04/12/2001	Michael F. Weiser	B0410/7277	7619

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EXAMINER

HAMILTON, LALITA M

ART UNIT	PAPER NUMBER
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3624

DATE MAILED: 01/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/743,695

Applicant(s)

WEISER ET AL.

Examiner

Lalita M Hamilton

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on RCE filed on December 18, 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-7,9 and 11-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-7,9 and 11-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

RCE

A Request for Continuation (RCE) was filed on December 18, 2003. The RCE has been processed and a detailed

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2-3, 11-12, 20-21, 34-35, and 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Neuss (5,536,274).

Neuss discloses a spiral implant configured to resist migration comprising a flexible body having proximal and distal portions each defining a profile, the proximal portion prior to implantation having a larger profile than the distal portion (**fig.5: 1-2; col.2, lines 25-56; and col.7, lines 17-26**); the flexible body defines an exterior, a hollow interior, and at least one opening between the interior and exterior (**col.6, lines 45-54**); a surgical adhesive applied to the device (**col.4, lines 23-40**); the surgical adhesive is associated with the device after the device is implanted in tissue (**col.4, lines 23-40**); individual coils of the helical spring have a constantly increasing diameter from the distal portion to the proximal portion (**fig.5**); coils of the distal portion define a constant diameter and coils of the proximal portion define an increasing diameter in the

proximal direction (**fig.5**); the helical spring is formed from a filament having a non-circular cross-sectional shape (**col.2, lines 35-40**); the cross-sectional shape of the filament is rectangular (**col.2, lines 35-40**); and the flexible body comprises a helical spring (**col.6, lines 45-55**).

Claim 49 is rejected under 35 U.S.C. 102(a) as being anticipated by Hussein (5,810,836).

Hussein discloses an implant device and method of implanting comprising the steps of providing a flexible spring body implant having sufficient longitudinal flexibility to absorb migratory forces applied on the device by surround tissue after implantation and inserting the flexible spring into the tissue (**col.2, line 47-48**) and (**col.3, lines 35-40**).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4-7, 18-19, 22-24, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neuss in view of Barnhart (5,893,864).

Neuss discloses the invention substantially as claimed; however, Neuss does not disclose a tail at the proximal portion; the tail defines a profile that is larger than the distal portion of the body; the tail is configured to remain at the tissue surface when the device is implanted; the tail is configured to be implanted in the tissue when the body of

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the device is implanted; the tail is formed by a more broadly wrapped coil adjacent to the proximal portion of the body forming an arm that extends laterally from the longitudinal axis of the device in the diameter of coils that comprise the body; the flexible body comprises a helical spring and the tail is deformed to be out of plane with the helical orientation of coils comprising the body of the spring; the tail comprises a broadly wound most proximal coil of the spring having a diameter that is greater than the diameter of coils of the body of the device; the broadly wound coil is concentric with the body of the device; or the broadly wound coil has a center which is offset from the longitudinal axis of the body of the device. Barnhart teaches a spiral device comprising a tail at the proximal portion (**fig.1: 27**); the tail defines a profile that is larger than the distal portion of the body (**fig.1: 27**); the tail is configured to remain at the tissue surface when the device is implanted (**fig.1: 27- tail has the capability of being configured to remain at the tissue surface**); the tail is configured to be implanted in the tissue when the body of the device is implanted (**fig.1: 27- tail has the capability of being configured to be implanted**); the tail is formed by a more broadly wrapped coil adjacent to the proximal portion of the body forming an arm that extends laterally from the longitudinal axis of the device in the diameter of coils that comprise the body of the spring (**fig.1: 20 and 27**); the flexible body comprises a helical spring and the tail is deformed to be out of plane with the helical orientation of coils comprising the body of the spring (**col.3, lines 25-50- can be configured to be out of plane**); the tail comprises a broadly wound most proximal coil of the spring having a diameter that is greater than the diameter of coils of the body of the device (**fig.1: 20**); the broadly

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wound coil is concentric with the body of the device (**fig.1: 20**); and the broadly wound coil has a center which is offset from the longitudinal axis of the body of the device (**col.3, lines 25-50- it can be configured to be off center**). It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate a tail at the proximal portion; the tail defines a profile that is larger than the distal portion of the body; the tail is configured to remain at the tissue surface when the device is implanted; the tail is configured to be implanted in the tissue when the body of the device is implanted; the tail is formed by a more broadly wrapped coil adjacent to the proximal portion of the body forming an arm that extends laterally from the longitudinal axis of the device in the diameter of coils that comprise the body; the flexible body comprises a helical spring and the tail is deformed to be out of plane with the helical orientation of coils comprising the body of the spring; the tail comprises a broadly wound most proximal coil of the spring having a diameter that is greater than the diameter of coils of the body of the device; the broadly wound coil is concentric with the body of the device; and the broadly wound coil has a center which is offset from the longitudinal axis of the body of the device, as taught by Barnhart into the device disclosed by Neuss, to further assist the device in resisting migration once in place.

Claims 9, 13-15, 36-37, and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neuss.

Neuss discloses the invention substantially as claimed and further discloses a flexible body comprising a helical spring (**col.6, lines 45-55**); the helical spring has varying flexibility along its length (**col.3, lines 1-13**); the helical spring is formed from a

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filament having varying modulus of elasticity (**col.3, lines 1-13- flexibility/elasticity based on type of material used**); and the filament is comprised of a plurality of materials of varying moduli of elasticity (**col.2, lines 25-56**). It is inherent that the may be configured to resist migration by exhibiting longitudinal flexibility to substantially absorb migratory forces, since the device is made of flexible/elastic components. It is inherent that the major axis of the rectangular cross-section may be substantially perpendicular to the longitudinal axis of the device and that the major axis of the rectangular cross-section may be at an acute angle to the longitudinal axis of the device, since it is disclosed that device may be configured in numerous manners. It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate a device configured to resist migration by exhibiting longitudinal flexibility to substantially absorb migratory forces and that the major axis of the rectangular cross-section may be substantially perpendicular and/or acute to the longitudinal axis of

Claims 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neuss in view of Cottenceau (5,484,424).

Neuss discloses the invention substantially as claimed; however, Neuss does not disclose varying flexibility is created by varying the distance between individual coils of the helical spring or the helical spring being formed from a filament having a varying thickness along its length, which creates varying flexibility along the length of the helical spring. Cottenceau teaches a spiral device having varying flexibility is created by varying the distance between individual coils of the helical spring and the helical spring

being formed from a filament having a varying thickness along its length, which creates varying flexibility along the length of the helical spring (**fig.13-14 and col.5, lines 25-36**). It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate varying flexibility is created by varying the distance between individual coils of the helical spring and the helical spring being formed from a filament having a varying thickness along its length, which creates varying flexibility along the length of the helical spring, as taught by Cottenceau into the device disclosed by Neuss, to help prevent migration of the device when it is in place.

Claims 25-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neuss and Barnhart as applied to claim 22 above, and in further view of Whalen (4,130,904).

Neuss discloses and Barnhart teaches the invention substantially as claimed; however, neither reference discloses nor teaches a tail that includes a proximal end that is secured to the broadly wound coil, the proximal end joined to the broad loop by being wrapped about the loop, or the proximal end joined to the broad loop coil by welding or a malleable sleeve. Whalen teaches a flexible helical spring (**col. 1, lines 48-53**) comprising a helically wound coil having a proximal end secured to the broadly wound coil (**fig.2: 30 and 34**), the proximal end joined to the broad loop coil by being wrapped around the loop (**fig.2**), and welding as a means of securing (**col.2, lines 40-45**). It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate a tail that includes a proximal end that is secured to the broadly wound coil and the proximal end joined to the broad loop by being wrapped

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about the loop, as taught by Whalen into the device disclosed by Neuss and taught by Barnhart, in order to provide a means of maintaining the coils in a circular shape; it would have been obvious to one having ordinary skill in the art at the time the invention was made to join the proximal end to the broad loop coil either by welding or a malleable sleeve as alternative means of securing.

Claims 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neuss, Barnhart, and Whalen as applied to claim 25 above, and in further view of Hussein (5,810,836).

Neuss discloses and Barnhart and Whalen teach the invention substantially as claimed; however, none of the references disclose nor teach a neck portion comprising a straight line segment that lies in a plane substantially parallel to the longitudinal axis of the device. Hussein teaches a stent comprising a helical body having a neck portion having a straight-line segment (**fig.5**) and lying in a plane substantially parallel to the longitudinal axis of the device. It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate a neck portion comprising a straight line segment that lies in a plane substantially parallel to the longitudinal axis of the device, as taught by Hussein into the device disclosed by Neuss and taught by Barnhart and Whalen, to provide an alternative means of preventing migration of the device.

Claims 38-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hussein in view of Neuss.

Hussein discloses an implant device and method of implanting comprising the

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steps of providing an implant device having a flexible body with the proximal and distal ends and an anchoring tail at the proximal tail (**col.2, lines 30-31 and 47**) and (**fig.8a-l**), providing a sharp tip delivery device configured to penetrate tissue and releasably retain the tissue implant device (**43**), associating the implant device with the implant delivery device, accessing the desired tissue implant site, withdrawing the implant delivery device from the implanted implant device, the implant and delivery device is rotated while penetrating forces are applied to screw the device into the tissue (**col.4: 2**), the tail of the implant device is submerged below the surface of the tissue after implantation (**fig.8i**), providing a tissue implant device that does not migrate from the tissue after implantation (**col:2, lines 30-36 and col.3, lines 36-39**), the device delivered surgically to the intended tissue location, providing a flexible spring body implant device having sufficient longitudinal flexibility to absorb migratory forces applied on the device by surrounding tissue after implantation, inserting the flexible spring body into the tissue (**col.2, line 47 and col.3, lines 35-40**), and an alternative embodiment where the implant remains exposed at the surface of the tissue after implantation (**fig.1**); however, Hussein does not disclose a body having a proximal portion and a distal portion each defining a profile and wherein the profile of the proximal portion is larger than the distal portion, the device being delivered percutaneously or transthoracically, applying a penetrating force to the implant and implant delivery device combination such that the combination penetrates tissue to a clinically effective penetration depth to implant the device, or applying adhesive to the body prior to implantation. Neuss teaches a spiral implant comprising a body having a proximal portion and a distal portion each defining a

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profile and wherein the profile of the proximal portion is larger than the distal portion (fig.5: 1 and 2; col.2, lines 25-56; and col.7, lines 17-26) and applying adhesive to the body prior to implantation (col.4, lines 23-40). It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate a body having a proximal portion and a distal portion each defining a profile and wherein the profile of the proximal portion is larger than the distal portion and applying adhesive to the body prior to implantation, as taught by Neuss into the device disclosed by Hussein, to prevent the device from migrating when in place.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate the method of delivering the device percutaneously and transthoracically in order to provide an alternative means of delivery and to apply a penetrating force to the implant and implant delivery device combination in order to ensure that the combination penetrates tissue to a clinically effective penetration depth to implant the device.

Response to Arguments

Applicant's arguments with respect to claims 2-7, 9, and 11-51 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.


Jacobsen (5,911, 717)
Hobbs (6,059,825)
Shifrin (5,476,471)

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lalita M Hamilton whose telephone number is (703) 306-5715. The examiner can normally be reached on Tuesday-Thursday (8:30-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vincent Millin can be reached on (703) 308-1065. The fax phone number for the organization where this application or proceeding is assigned is (703) 746-6101.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-2272.



LMH



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